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10/695,586	10/28/2003	Christopher Shawn Bartimus	CB104	5376

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT PAPER NUMBER

3733

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,586

Applicant(s)

BARTIMUS, CHRISTOPHER
SHAWN

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/28/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site <http://www.uspto.gov> in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Claim Objections

Claims 8-10 are objected to because of the following informalities: In claim 8, it appears that applicant intends to claim a clamping block having a flat surface with rounded edges. Examiner suggests using the word --comprising—rather than the phrase "configured to"; since the phrase "configured to" implies functionality, and the claimed "clamping block" would only have to be capable of having a flat surface and rounded edges. The claimed clamping block will be considered to comprise a flat surface and rounded edges for examination purposes.

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Claims 9-10 are objected to because of the following informalities: In claim 9, it appears that applicant intends to claim a clamping block defining at least one access opening. Examiner suggests using the phrase --said clamping block defines at least one access opening-- rather than the phrase "configured to define at least one access opening", since the phrase "configured to" implies functionality, and the claimed "clamping block" would only have to be capable of defining at least one access opening. The claimed clamping block will be considered to define at least one access opening for examination purposes.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the cross member connector" in line 1.

There is insufficient antecedent basis for this limitation in the claim. It appears applicant intended to state, "the cross arm connector" rather than "the cross member connector". Appropriate correction is required. Examiner will consider the "cross member connector" to be the "cross arm connector" for examination purposes.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim

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language. This claim is an omnibus type claim. The phrase "the embodied mechanism" makes this an omnibus type claim.

Claim 18 contains many limitations that lack antecedent basis, for example, "the location", "the pilot holes", "the pedicle screws", "the alignment limitations", "the holes in the connector", "the disk space", etc. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Krag (US Pat. 6,231,575 B1).

Krag discloses a multi-axial fixation device for use in aligning spinal members during operation, the device comprising: a clamping block (Fig. 1 below) the clamping block defining a passageway (Fig. 1 below), the passageway configured to receive a cross member therein, the clamping block having a clamping block connector (Fig. 1 below) connected thereto, and the clamping block connector is capable of connection with a first spinal member.

In claim 1 there exists an inconsistency between the language in the body of the claim, thus making the scope of the claim unclear. In line 3, applicant

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recites "a clamping block" with the cross member being only functionally recited, i.e. "...configured to receive a cross member therein ..." and the locking device also being only functionally recited "...said cross member configured for variable locked positioning within said clamping block by a locking device...", thus indicating that the claim is directed to the subcombination, "a clamping block". However, in line 7, applicant positively recites the cross member as part of the invention, i.e. " ...said cross member configured for insertion...having a cross arm connector..." and in line 11 applicant positively recites the locking member as part of the invention, thus indicating that the combination, a clamping block, a cross member and a locking device is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claim 1 will be considered as being drawn to the combination, a clamping block, a cross member and a locking device

The cross member is capable of insertion within the passageway (Fig. 1 below), the cross member having a cross arm connector (Fig. 1 below) connected thereto, the cross arm connector configured to connect with a second spinal member, the cross member configured for variable locked positioning within the clamping block by a locking device (Fig. 1 below); the locking device is capable of allowing the cross member to be variously adjustably positioned and held within the clamping block; the clamping block, the locking device and the

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cross member are capable of allowing variable positioning and locking of the cross member thereby allowing multiple adjustable positioning of the spinal members. The locking device comprises a plurality of stacked portions (the portions of the cross member, the set screw, and the clamping block involved in locking the device, Fig. 1) that are configured to lock and hold the cross member by compressive force upon the stacked portions. The passageway is a transverse multi-positional opening through the clamping block. The passageway extends through the clamping block and the cross member can be swiveled in the passageway and can be locked in a variety of positions, hence the passageway is a transverse, multi-positional opening through the clamping block. A cross arm connector and the clamping block connector are each capable of connecting with a spinal member through the use of a pedicle screw (Fig. 1). The cross member connector further comprises a safety stop (Fig. 7 below); the safety stop is capable of preventing withdrawal of the cross member from the passageway. The locking device is multiply adjustable through the use of a set screw (Fig. 1 below). The clamping block further defines an aperture (Fig. 1 below) configured to maintain and hold the set screw within the clamping block. The clamping block is configured to have a flat surface with rounded edges (Fig. 2) and is capable of preventing discomfort that may be experienced by the recipient. The clamping block is configured to define at least one access opening, the access opening capable of allowing the passage of body fluids around the clamping block. The access opening can be considered to be the aperture through which the clamping block connector is connected to the clamping block

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(as seen in Fig. 4 below, ref. 56 from US Pat. 5,741,255, incorporated by reference in column 2, lines 41-43). The device further comprises a retaining clip, the retaining clip configured to allow the locking device to be retained and removed from within the clamping block. The retaining clip can be considered to be the thread of the set screw (Fig. 1 below). The cross member passes through the passageway (Fig. 1) and the locking device is capable of allowing variable linear, rotational, and angular positioning of the cross member. The angles and location of the cross member connector and the clamping block connector are capable of being used in series and combination for use in multiple level fusions and bridging. The locking device is capable of postoperative access by a non-invasive means to accomplish a variety of postoperative adjustments. The device is capable of allowing selective disengagement and adjustment of the spinal members in one direction while retaining the spinal members in a secured position in a second direction.

With regard to the statements of intended use and other functional statements (e.g. "... configured to allow the cross member to be variously adjustably positioned...", "...configured to prevent withdrawal of the cross member...", "...configured to maintain and hold the set screw...", "...configured for use in series and combination for use in multiple level fusions and bridging...", etc.), they do not impose any structural limitations on the claims distinguishable over the device of Krag, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not

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require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

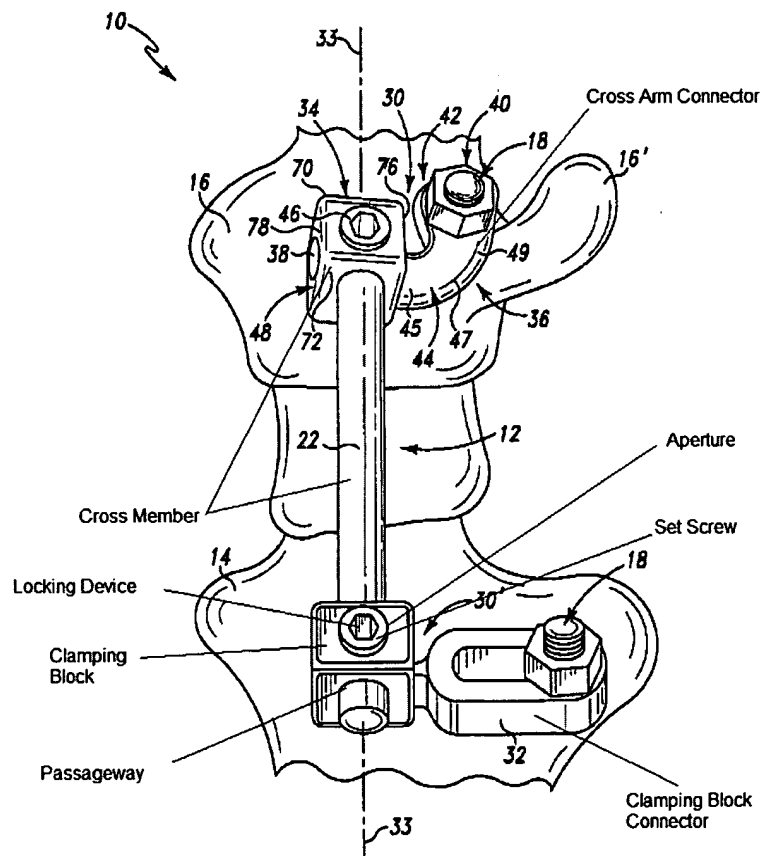
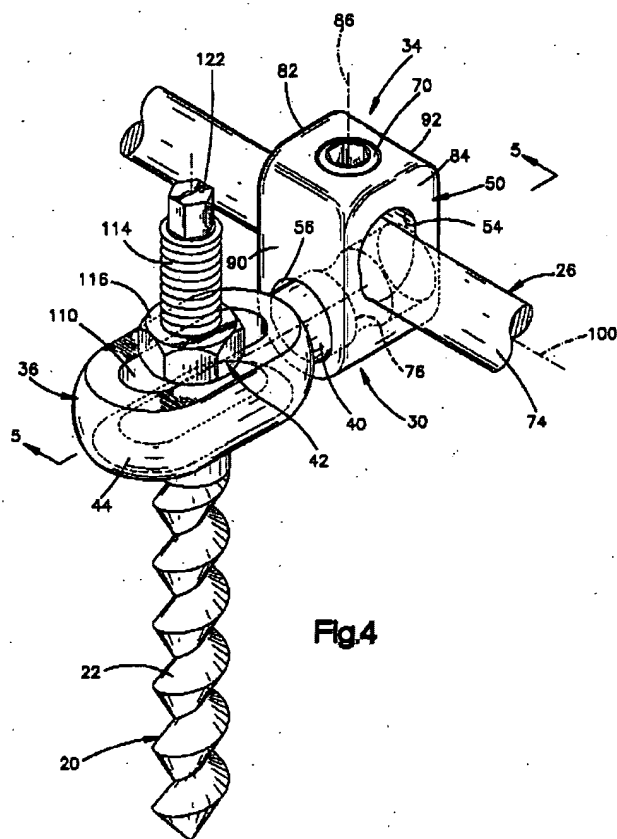


Fig. 1

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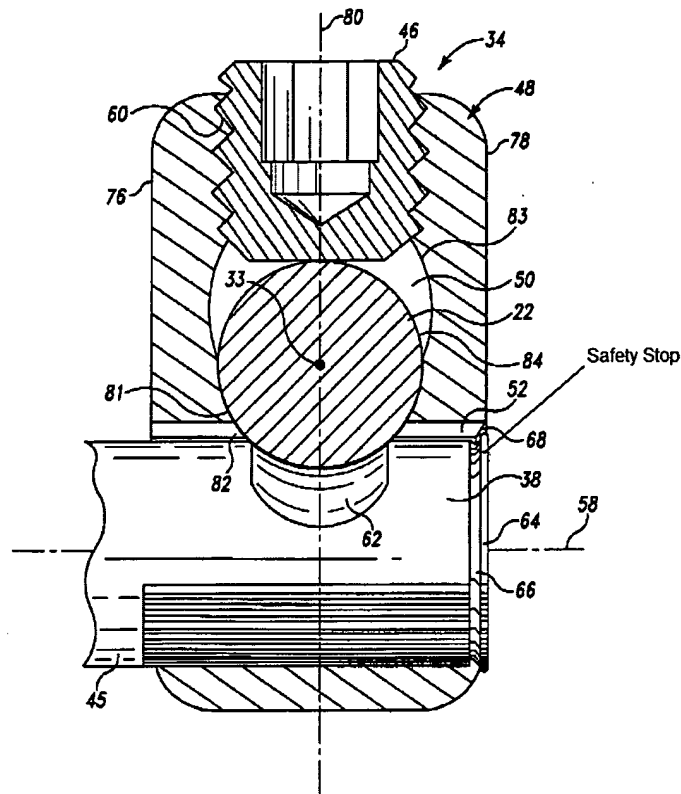


Fig. 7

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krag (US Pat. 6,231,575 B1) in view of Biedermann et al. (US Pat. 5,961,517).

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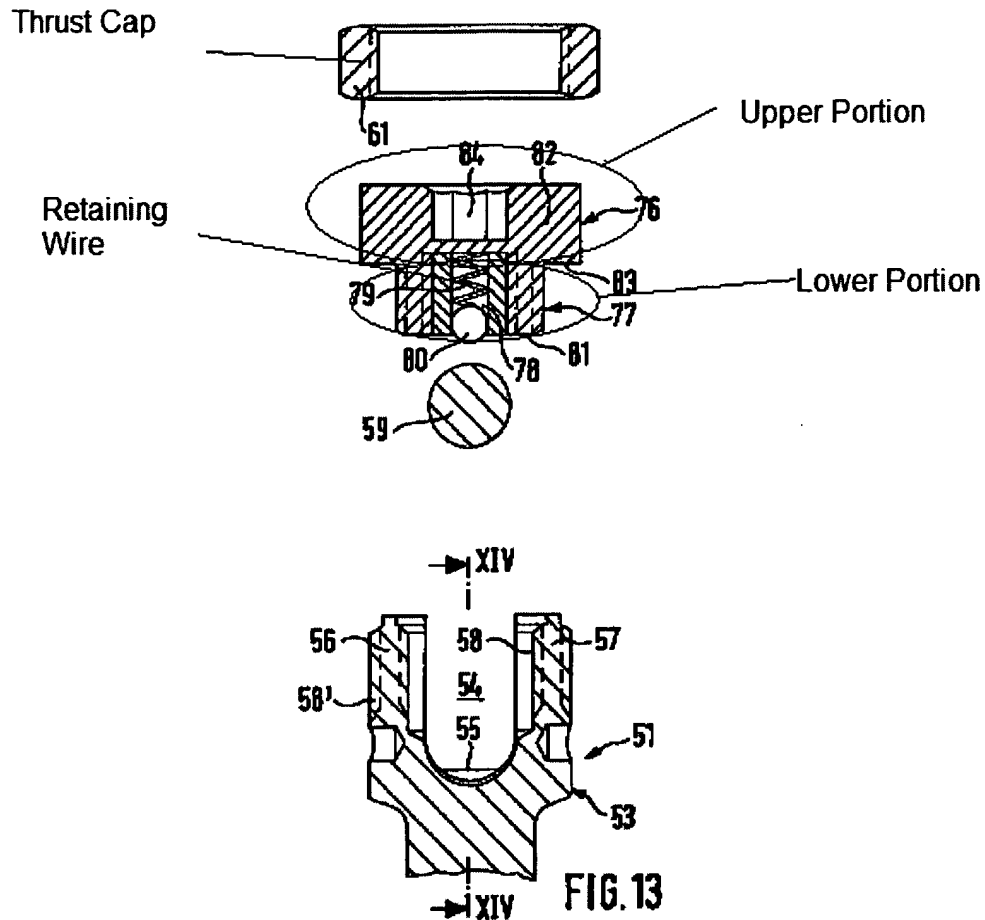
Krag discloses the claimed invention except for the locking device comprising: a thrust cap, an upper portion and a lower portion, the thrust cap the upper portion and the lower portion each having a radius configured to interact with an adjoining portion when placed in a desired position and orientation, the upper portion and the lower portion each having a radius center and configured so that the radius centers are offset when the upper portion and the lower portion are placed in correct alignment within the clamping block. The thrust cap is held in position by a retaining wire configured to retain the thrust cap from sliding out of the clamping block and preventing the whole system from disassembling when in a loosened state.

Biederman et al. disclose: a thrust cap (Fig. 13 below), an upper portion (Fig. 13 below) and a lower portion (Fig. 13 below), the thrust cap the upper portion and the lower portion each having a radius configured to interact with an adjoining portion when placed in a desired position and orientation, the upper portion and the lower portion each having a radius center and configured so that the radius centers are offset when the upper portion and the lower portion are placed in correct alignment within the clamping block. The thrust cap is held in position by a retaining wire (Fig. 13 below) configured to retain the thrust cap from sliding out of the clamping block and preventing the whole system from disassembling when in a loosened state. The thrust cap, upper portion and lower portions are used in order to obtain a rigid connection between the anchoring member and the rod and also to allow an easy manipulation for precisely

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adjusting the position between the anchoring member and the rod before finally locking the position (abstract, lines 11-17).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the locking mechanism of Krag with the thrust cap, upper portion, lower portion, and retaining wire of Biedermann et al. This would help to create a more rigid connection between the cross member of Krag and the clamping block of Krag, and furthermore would allow an easy manipulation for precisely adjusting the position between the cross member of Krag and the clamping block of Krag before finally locking the position of the multi-axial fixation device (Biederman, abstract, lines 11-17).



With regard to claim 14, Krag discloses the claimed invention except for the safety stop being located on the cross connector. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the safety stop on the cross connector rather than the cross arm

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connector, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

The device of Krag in view of Biedermann et al. is capable of performing an improved method for posterior spinal fixation comprising: preparing the location for the embodied mechanism by removal of bone or unnecessary obstructions for the desired positioning (column 2, lines 36-39); placing a fixation device in the prepared location and drilling the pilot holes for the pedicle screws within the alignment limitations of the fixation device using the holes in the connectors of the embodied mechanism as a guide for angles and placement (column 2, lines 18-24), the fixation device having a clamping block (Fig. 1 above), the clamping block defining a passageway (Fig. 1 above), the passageway configured to receive a cross member therein (Fig. 1 above), the clamping block having a clamping block connector connected thereto (Fig. 1 above), the clamping block connector configured for connection with a first spinal member (Fig. 1 above), the cross member configured for insertion within the passageway (Fig. 1 above), the cross member having a cross arm connector connected thereto (Fig. 1 above), the cross arm connector configured to connect with a second spinal member (Fig. 1 above), the cross member is for variable locked positioning within the clamping block by a locking device, since it can swivel (Fig. 4 above from US Pat. 5,741,255, incorporated by reference in column 2, lines 41-43), the locking device is configured to allow the cross member to be variously adjustably positioned and held within the clamping block,

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since it can rotate and slide in its respective aperture (Fig. 4 above from US Pat. 5,741,255, incorporated by reference in column 2, lines 41-43); the clamping block, the locking device and the cross member are configured to allow variable positioning and locking of the cross member thereby allowing multiple adjustable positioning of the spinal members, since the cross member can slide in the clamping block when not in a locked position (Fig. 4 above from US Pat. 5,741,255, incorporated by reference in column 2, lines 41-43); affixing pedicle screws or anchoring device as presently used in the field to each side of the disk space to be bridged (Fig. 1 above), attaching the embodied mechanism on the threaded pedicle screws with nuts (Fig. 1 above); aligning the spine across the affected disk space to be anatomically correct (column 2, lines 15-16) and tightening the set screw (column 3, lines 14-19); and making adjustments postoperatively by a non-invasive procedure if necessary (column 6, lines 8-11).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER